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Data Support and Research Recommendations

The committee has proposed principles to guide the use of Dietary Reference Intakes (DRIs) in selecting reference values for nutrition labeling and principles for the use of DRIs in discretionary food fortification. To measure the impact of the implementation of the guiding principles, it is necessary to design and conduct studies to better understand consumers' use of nutrition labeling with regard to dietary intakes and purchase decisions in the United States and Canada, as well as the impact that fortified foods have on nutrient intake. Without this information it is difficult to judge either the effects of nutrition labeling in instituting healthy changes in the diet or the need to fortify the food supply with additional nutrients. These efforts will require the expertise and collaboration of academia, industry, and government. Because food and dietary supplement composition and consumption in both countries continually change, these studies need to be ongoing.

The committee identified five specific areas where this additional research and data support would be of benefit: studies that would lead to the determination of requirements for those nutrients for which Estimated Average Requirements (EARs) could not be developed; more data of high quality on adverse effects and dose relationships to permit definition of the biological endpoints, no-observed-adverse-effect levels (NOAELs), and lowest-observed-adverse-effect levels (LOAELs) underlying the Tolerable Upper Intake Levels (ULs); empirical research to ascertain the impact of discretionary fortification practices; regular collection of food and dietary supplement intake information and enhancement of current food composition

and dietary supplement databases; changes in nutrition labeling and consumer research on its use.

RESEARCH IN SUPPORT OF DETERMINING NUTRIENT REQUIREMENTS

The DRI reports identified a set of research priorities for each nutrient (IOM, 1997, 1998, 2000b, 2001, 2002a). One priority was the need to establish EARs for nutrients where data were insufficient to set them at the time (e.g., vitamin D) (IOM, 1997). EARs have multiple uses. As mentioned in Chapter 6, without an EAR it is not possible to estimate the population prevalence of inadequacy for a nutrient following the approach used in the DRI assessment report (IOM, 2000a). The committee recommends that the U.S. Department of Health and Human Services (DHHS), the U.S. Department of Agriculture (USDA), and Health Canada promote and support basic research that will lead to the development of EARs that were not established by the DRI panels, especially for those nutrients that are deemed important for public health or for special populations. Nutrients currently without EARs include vitamin D, vitamin K, pantothenic acid, biotin, choline, calcium, chromium, fluoride, manganese, total fiber, linoleic acid, and α-linolenic acid.

The research needs are described in detail in the DRI volumes for each nutrient. In general, these research needs include studies to provide the basic data to construct risk and benefit curves across graded exposures to food- and supplement-based intake of a nutrient while monitoring a combination of response indices. They also point to the need for subpopulation-specific information even for those nutrients with EARs. For example, for vitamin C, vitamin, E, selenium, and β-carotene and other carotenoids, useful data are seriously lacking for setting requirements for adolescents, pregnant and lactating women, and the elderly (IOM, 2000b).

BIOLOGICAL ENDPOINTS UNDERLYING THE TOLERABLE UPPER INTAKE LEVELS AND INFORMATION ON ADVERSE EFFECTS

For many nutrients the DRI panels were unable to set ULs because data were not available on adverse effects that had been associated with high intakes of the nutrient from food sources (see Appendix C). Some nutrients clearly had adverse effects associated with doses of the nutrient either consumed as a dietary supplement or for treatment purposes, such as the development of neuropathy with high

doses of pyridoxine to treat carpal tunnel and premenstrual syndromes (Schaumburg et al., 1983, as cited in IOM, 1998). With the neuropathy related to high-dose treatments of pyridoxine, there was sufficient scientific documentation for the panel to identify a NOAEL and a LOAEL to derive a UL for adults and to address specific issues based on limited data related to the life stage groups of those under 19 years of age, pregnancy, and lactation (IOM, 1998). Because pyridoxine had been used as a single-treatment modality at high doses, the relationship could be identified. With other nutrients, more often the case was that the data were too limited to clearly demonstrate a relationship between the biological endpoint and the dose or duration of treatment. With pyridoxine, a dose-response relationship and the development of neuropathology had been well described in animal studies prior to the first reports in humans (Phillips et al., 1978, as cited in IOM, 1998). While the LOAEL and NOAEL for pyridoxine were identified based on human studies, the animal data served to confirm the dose cut-points.

The ability to set a UL for a nutrient is particularly important for discretionary fortification. For most nutrients there is limited indication that the UL could be reached through the intake of nutrients from conventional food marketed for the general population 4 years of age and older. The risk may be greater for food marketed to specific life stage and gender groups and through the prolonged use of high doses of dietary supplements either as part of the overall diet or for treatment purposes. The committee recommends that support for research on adverse effects become a high priority for those nutrients for which no UL could be established and for which initial data indicate that the general population or particular life stage and gender groups may be at risk from high intakes.

In addition, the committee recommends that the Food and Drug Administration and Health Canada expand their educational efforts to help consumers and health care professionals clearly understand the breadth of possible adverse effects, the information needed to identify a relationship between a food or dietary supplement and an adverse effect, and the best process for accurately reporting this information.

EMPIRICAL RESEARCH TO ASCERTAIN THE IMPACT OF DISCRETIONARY FORTIFICATION

There is an urgent need for empirical research to determine the impact of discretionary fortification practices on the distribution of usual nutrient intakes and on the prevalence of nutrient inadequacy

and nutrient excess in the population. The USDA food composition database is not designed to facilitate the tracking of discretionarily fortified food products in intake surveys. The committee understands that USDA is currently working to address this issue and encourages continuation of that effort. Such research is needed to form a sound scientific basis for future nutrition labeling and discretionary fortification policies. This research would require cooperation between industry and government agencies such as was done on a smaller scale by Berner and colleagues (2001). Only those fortified products consumed by a significant percentage of the population should be considered for this research and related database expansions unless a particular product is consumed almost exclusively by a specific ethnic or economic population subgroup. In this way the sociodemographic and behavioral characteristics of the population subgroups whose usual intakes are most likely to be affected by discretionary fortification may be determined. Research is also required to determine the optimal levels for discretionary fortification and the selection criteria for food vehicles that are likely to have the greatest impact on the lower or upper ends of the intake distribution.

FOOD COMPOSITION AND DIETARY SUPPLEMENT DATABASES

Specific data are necessary for a complete and accurate assessment of nutrient adequacy and excess. In particular there is a vital need to maintain current and representative databases for food and supplements that can be used to effectively assess nutrient intakes. Complete databases that reflect current fortification practices are critical to accurately assess the nutrient content of the food supply, population food intakes, and the effects of dietary intake on health outcomes. To do this, the databases must be up-to-date to ensure there are no missing values and that the nutrient data within the databases are current. As mentioned in Chapter 6, the prevalence of nutrient inadequacy could be grossly overestimated if there are high levels of underreporting in the dietary intake data or if the food composition databases include incomplete or erroneous data on the levels of a particular nutrient in food. With the new DRIs the quantifying units of measure also may need to be updated in the databases. In those instances where computerized nutrient databases serve as data sources for nutrition labeling, care should be taken to ensure that those databases are the same ones used with dietary surveys of the United States and Canadian populations. This

may require harmonization or cross-verification of databases. The application of bioinformatics (classification, manipulation, and retrieval of data) in support of food and supplement databases in both countries would contribute substantially to the accuracy and the ease of use of these databases.

Research on methodologies for the sampling and analysis of food and its constituents is warranted. Consideration must be given to the food matrix, not just the chemical constituent under analysis, as there is impetus from the DRI macronutrient report (IOM, 2002a) to consider fiber and sugar sources as natural or added to food or supplements. The development of valid analytical techniques for differentiating dietary fiber from functional fiber and added sugars from naturally occurring sugars in food and dietary supplements is essential. Other important parameters for this research include how added sugars might contribute to appetite regulation, total energy intake, and nutrient density.

CHANGES IN NUTRITION LABELING AND CONSUMER RESEARCH ON ITS USE

A problem faced by the committee was the paucity of data on consumer use of nutrition labeling, especially on the reference nutrient values. The committee expects that the regulatory agencies will use the guidelines and recommendations in this report in a systematic process to revise the scientific basis for nutrition labeling and for discretionary fortification. As part of this process the committee also recommends a general review of nutrition labeling, as well as significant consumer-based research on the understanding and use of nutrition labeling found on conventional food and supplements.

Nutrition Labeling

As the rules are modified to accommodate changes in the reference values, other changes should be considered. First, the committee recommends that the original intent of the Nutrition Facts box should be reevaluated to determine whether and how it should be modified. Second, a number of elements of nutrition labeling warrant review: the order in which nutrients are listed on the label, which nutrients should be included, the relative emphasis on macro- and micronutrients, the emphasis within macronutrients, the way in which the label may contribute to positive behaviors that address the increase of overweight and obesity in North America, the importance of the position and size of the Nutrition Facts box on the

food label, and harmonization of the serving sizes on the Nutrition Facts box and other dietary recommendations such as the Food Guide Pyramid. Third, the committee encourages the regulatory agencies to assess the potential impact of changing the Nutrition Facts box on the response of food manufacturers with respect to the composition of products and the development of new products, including the use of biotechnology. Finally, the committee encourages that advance planning for nutrition labeling is put into place by the regulatory agencies to ensure that the process from proposals to final rules is timely.

Research on the Use of Nutrition Labeling to Inform Consumer Decisions

The Nutrition Facts box has been in the marketplace for nearly a decade, and it is likely that the way in which consumers use the information it provides has changed over time. The committee found a paucity of current research on all aspects of consumer use and understanding of the Nutrition Facts box. In the United States, research primarily was conducted around the times of regulatory change in the early 1970s and in the early 1990s.

Data from more recent studies (Kreuter et al., 1997; Neuhouser et al., 1999; Perez-Escamilla and Haldeman, 2002) suggest that the Nutrition Facts box has had a positive effect on the quality of the diets of some population groups, but information has been limited since the beginning of nutrition labeling in the 1970s. Further, the committee has been unable to identify studies that provide a comprehensive view of current usage patterns. One recent web-based, nationally representative sample survey of primary household shoppers 18 years of age and older found that when consumers use the current Nutrition Facts box to evaluate the nutritional quality of a product, they tend to rely on a variety of components, such as calories, total fat, sodium, and saturated fat. However this study was designed for the specific purpose of assessing the impact of *trans* fat label information on consumer food choices (Cogent Research, 2003). Some studies suggest that it is important to proceed cautiously in making modifications to nutrition labeling (IOM, 2002b) since consumers may focus on new information when making purchasing decisions and ignore basic information that may be equally important. This behavior was confirmed in the recent *trans* fat label information study (Cogent Research, 2003). It would seem relevant to understand how different segments of the population are using nutrition labels and, in particular, the extent to which the percent

Daily Values (% DV), rather than absolute amounts, contribute to consumers' purchase decisions and their overall diet quality.

Even less consumer research has been conducted on the Supplement Facts box. Therefore research also is needed to understand how consumers use this information. In addition, studies that compare the relative consumer use and understanding of both the Nutrition and the Supplement Facts boxes would enhance the ability of the agencies to revise both labels to better meet consumer needs.

The committee has identified 14 questions that could frame development of much-needed consumer research on nutrition labeling:

- To what extent do consumers use the Nutrition Facts box?
- How does use of nutrition labeling differ by ethnic, life stage, and gender groups?
- How does use of nutrition labeling differ with first-time purchases and with increased label use?
- To what extent do consumers understand the concept of the Daily Value (DV) and do they use it to make purchase decisions?
- Do consumers understand the difference between nutrients (e.g., calcium) for which the % DV is on the label to help them reach a positive goal for intake, and other nutrients (e.g., cholesterol) for which the % DV is on the label to help them reduce their risk of chronic disease?
- To what extent do consumers use the information in the Nutrition Facts box to confirm information they read on the front of the package, including nutrient content and health claims?
- Is the current format of the Nutrition Facts box the most effective manner to convey the information that consumers state that they use, as well as to convey the information that health professionals indicate is important clinically, such as absolute amounts?
- Is there a need to modify the Nutrition Facts box for food and supplements marketed to special populations, such as the elderly?
- Would changes in levels of the DVs based on EARs impact food choices, especially in high-risk groups, such as children participating in the Special Supplemental Nutrition Program for Women, Infants and Children?
- Would the repercussions to changing the current format, such as consumer confusion, outweigh the positive communication benefits of a revised label format?
- Specifically in Canada, what will be the effects of introducing a new label format into the marketplace and of any additional changes that may be necessitated as a result of incorporation of new DVs into the label?

- What are the influences of and the roles for the Nutrition Facts box on overall diet quality?
- What is the role of the Nutrition Facts box in the larger context of nutrition education to affect consumer behavior?
- Are there novel ways that can be identified for using the Nutrition Facts box to teach consumers about nutrition?

Addressing such questions will require a comprehensive approach that includes both quantitative and qualitative methods as commonly employed in market research. This research should provide information about different population groups stratified by traditional factors, such as age, gender, and educational level, and it also should examine how individuals who either have diet-related diseases or are at high risk for developing them use nutrition labeling to inform their purchases. Understanding how consumers use labeling information to inform purchase decisions will require the use of traditional survey techniques, accepted methods of qualitative research, and innovative techniques, such as the verbal protocol analysis described by Higginson and colleagues (2002).

The information obtained from this research should guide the development of a comprehensive food label communication plan that includes the Nutrition Facts box, other information provided on the label (including the ingredients list and health claims) and that integrates this information to help consumers choose more healthful diets. Such a communication plan should include increased broad consumer education on the use of the label, and it should have specified behavioral outcomes that may differ for the various populations of interest. In this manner new and emerging science and data from consumer research may provide the opportunity for a more comprehensive government-based communication and consumer education approach for using the Nutrition Facts box to improve food selection.